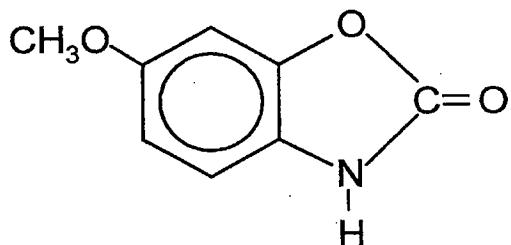


**REMARKS**

Claims 93-103 and 107-113 are pending, wherein claims 93-102 and 107-108 have been amended and new claims 109-113 were added. Reconsideration and allowance for the above-identified application are now respectfully requested in view of the foregoing amendments and the following remarks.

The independent claims are 107 and 110.

Claim 107 as now presented claims a process for promoting weight loss in a mammal by the administration of an amount of a composition comprising 6-methoxy-2,3-benzoxazolinone defined as:



or a pharmaceutically acceptable salt thereof sufficient to promote weight loss in said mammal, wherein said administered composition comprises a daily dosage of between about 5 mcg and about 60 mg of said 6-methoxy-2,3-benzoxazolinone, wherein said composition is obtained from at least one of (i) a leafy and/or immature plant part of one or more monocotyledonous plants or (ii) chemical synthesis. Support for obtaining the composition from the leafy and/or immature plant part of a monocotyledonous plant and/or by chemical synthesis is found at page 14, lines 1-3; page 22, lines 8-12.

The applied art neither teaches nor suggests the combination of elements recited in claim 107 as amended. The Office Action alleges that claims 93-103 and 107-108 are anticipated by US 2004/0038909 to Chawan under 35 U.S.C. § 102(e). First, Applicants wish to point out that the earliest filing date to which the present Application claims priority is April 13, 2000 (US Provisional No. 60/196,829) and that it also claims priority to another U.S. application that was filed April 13, 2001 (US Application No. 09/834,592). To the extent that either of these priority applications discloses the claimed embodiments, the present application is entitled to a filing date that is earlier than the filing date of Chawan, which is August 23, 2002. Accordingly, Chawan may not even be prior art to some of all of the claims recited herein.

Second, Chawan neither teaches nor suggests administering the claimed composition in an amount so as to promote weight loss in a mammal. Instead, Chawan discloses a method for treating overweight or obese persons in which certain high glycemic index, starch-containing foods, which are known to promote *weight gain*, are treated or modified with propylene glycol alginate to control the release of glucose into the patient's blood. Chawan, paragraph 1.

This is achieved by the introduction into the food composition of a hydrophilic food grade agent, such as *propylene glycol alginate*, which reduces the cooking losses and enhances the starch cell wall membrane to thereby slow the enzymatic hydrolysis of the gelatinized starch. The result is a steady state release of glucose and a net reduction in the blood glucose (glycemic index) relative to blood glucose observed in an overweight or obese patient having consumed comparable food composition without *propylene glycol alginate*.

*Id.* (emphasis added); see paragraphs 23-25, 28-30, 32-37, 39-41, 43-44, 50, 51, 53-59, 95, 107, 110, 113, 114. Other hydrophilic food grade agents that may be added to starch-containing foods are listed at paragraphs 114 and 115 of Chawan. Accordingly, the means by which Chawan treats overweight or obese persons is the addition of the hydrophilic food grade agent, such as propylene glycol alginate, to starch-containing foods in order to lower the glycemic index, not feeding the obese person the starch containing food by itself. In fact, Chawan expressly teaches that the "comparable food composition without propylene glycol alginate" results in a higher observed blood glucose level in an overweight or obese person. Paragraph 1. Nowhere does Chawan teach or suggest the use of the composition recited in the claims of the present Application as an example of the "hydrophilic food grade agent" used to treat starch-containing foods fed to overweight or obese persons.

Chawan discloses various examples of starch-containing foods from which a "meal" can be prepared and which can be modified by adding propylene glycol alginate. These include foods prepared or derived from tapioca, potato, wheat, rice, barley, oat, corn, and cereal grain. Paragraphs 36, 45, 56, 58. Because the foregoing foods contain starch, they are examples of the types of foods that would otherwise promote obesity and weight gain in the absence of being treated with propylene glycol alginate. They are certainly not examples of foods that promote weight loss. Common experience shows that corn products, for example, are routinely consumed by overweight and obese people but do not in themselves promote weight loss. Nor does Chawan even claim that they do.

In rejecting the claims of the present Application, the Office Action erroneously interprets Chawan in general, and claim 7 in particular, as disclosing the use of a monocotyledonous plant such as corn to treat overweight or obese persons. Based on a proper understanding of Chawan, as explained above, the opposite is true. According to Chawan, starch-containing foods made from tapioca, potato, wheat, rice, barley, oat, corn, or cereal grain ordinarily have a high glycemic index that promotes weight gain but which can be beneficially lowered by adding to such foods a hydrophilic food grade agent, such as propylene glycol alginate, which is said to help overweight or obese persons lose weight. In the absence of the hydrophilic food grade agent, such as propylene glycol alginate, Chawan teaches that starch-containing foods such as corn promote weight gain in obese and overweight persons. This is simply common sense. In view of this, one may not reasonably conclude that corn, wheat or the other starch-containing cereals and food products disclosed in Chawan contain a sufficient quantity of the composition recited in the claims of the present Application so as to promote weight loss in a mammal. Otherwise, Chawan would not teach adding a hydrophilic food grade agent, such as propylene glycol alginate, in order to reduce the glycemic index and control glucose uptake. Chawan would simply teach nothing more than feeding an overweight or obese person starch-containing foods such as tapioca, potato, wheat, rice, barley, oat, corn, and cereal grain. That, of course, would be ridiculous and defy common sense.

Third, there is no evidence in the record that corn kernal (*i.e.*, the part of the corn plant ingested by humans and used to make a "meal") contain appreciable quantities of the composition recited in the claims of the present Application, let alone in quantities sufficient to promote weight loss in a mammal. Humans do not typically eat corn plants rather than corn kernal, and there is nothing in Chawan to suggest that the "meal" is made from a leafy and/or immature part of a corn plant containing the claimed composition. In support of the assertion that the "corn" disclosed in Chawan (*i.e.*, corn kernal used to make food for humans) inherently contains 6-MBOA, the Office Action refers to the specification of the present Application, which teaches that 6-MBOA "is known to be naturally-occurring in various concentrations in monocotyledonous plants, like corn. As a result, 6-MBOA is inherently present in food compositions comprising corn, including the present invention."

The problem with the foregoing analysis is that it fails to distinguish between corn kernal, which are only produced by a fully mature corn plant and which constitute the only "corn" used to make food for humans, and the corn plant itself, which is what the present

Application describes as a good source of 6-MBOA and which is not typically ingested by humans. The present application makes it abundantly clear that 6-MBOA is most plentiful in young, immature plants that are not yet mature and seed-bearing. There is no teaching or suggestion in the art (or the present Application) that food made from corn kernals contains significant quantities of 6-MBOA.

Moreover, the food products referred to in Chawan are highly refined grain products, *e.g.*, “pasta, noodles, macaroni, spaghetti, rigatoni, ravioli, fettuccini, couscous, pancakes, waffles, breads, pizza, tortillas, taco shells …, breakfast cereals, pastries, rice-cakes, dough-wraps, and the like”. Paragraph 45. Thus, the “meal” referred to claim 7 of Chawan includes one or more of the highly refined grain products listed in paragraph 45. Because of the high level of processing required to make the foods listed in Chawan for feeding to obese and overweight people (*e.g.*, those listed in paragraph 45), even if corn or other grains initially contained sufficient quantities of 6-MBOA to promote weight loss in their raw, unprocessed condition, the highly processed and high glycemic index forms of the foods disclosed in Chawan clearly do not promote weight loss. Otherwise, Chawan would not teach the importance of adding a hydrophilic food grade agent such as propylene glycol alginate to help overweight or obese people lose weight when eating such foods. Accordingly, when properly understood, Chawan cannot be reasonably interpreted as disclosing or suggesting feeding an obese or overweight person corn products, such as bread, breakfast cereals, pastries and the like, to promote weight loss. Rather, Chawan teaches that such foods cause weight gain unless treated with a hydrophilic food grade agent, such as propylene glycol alginate, to reduce their glycemic index. This is consistent with common sense (*i.e.*, eating starchy foods typically causes weight gain, not weight loss).

Fourth, as further evidence that corn kernels or other seeds of monocotyledonous plants do not contain appreciable quantities of the composition recited in the claims of the present Application, and not in sufficient quantities to promote weight loss as claimed, Applicants submit herewith a copy of Epstein et al., “Dynamics of 6-Methoxybenzoxazolinone in Winter Wheat, Effects of Photoperiod and Temperature,” Journal of Chemical Ecology, Vol. 12, No. 10, 1986 (“Epstein Article”) (Attached as the Appendix). The present Application lists wheat and corn *plants* as examples of monocotyledonous plants that contain the composition recited in the claims. As plainly taught in the Epstein, “[u]nsprouted wheat seeds contain negligible amounts of 6-MBOA”. Abstract. The Epstein Article reports the authors’ “inability to detect significant

amounts of derivable 6-MBOA in wheat seeds" even though there are high concentrations of this compound in young wheat plants. Page 2018. While the Epstein Article does not state that 6-MBOA is not found in significant quantities in unsprouted corn kernels, it would be reasonable to extrapolate this conclusion, which is consistent with the teaching in Chawan that both wheat and corn food products promote weight gain, rather than weight loss, in the absence of adding a hydrophilic food grade agent, such as propylene glycol alginate, to reduce their glycemic index.

Finally, Chawan neither teaches nor suggests obtaining the composition recited in the claims "from at least one of (i) a leafy and/or immature plant part of one or more monocotyledonous plants or (ii) chemical synthesis". None of the corn based food products referred to Chawan (*e.g.*, breads, tortillas, taco shells, breakfast cereals, pastries, and dough-wraps) are made from leafy and/or immature corn plant parts. Humans typically do not eat corn plants (*e.g.*, stocks, leaves and roots), and Chawan does not teach any method in which corn plants, more particularly leafy and/or immature plant parts, or compositions therefrom, are ingested by a human in order to promote weight loss. Nor does Chawan teach or suggest obtaining the claimed composition by chemical synthesis. Thus, even if the "meal" made from "corn" in Chawan were to include 6-MBOA as alleged in the Office Action, Chawan still fails to teach or suggest the combination of elements recited in claim 107 as now presented.

In view of the foregoing, Applicants submit that claim 107 as now presented is patentable over the art of record. Dependent claims 93-103 and 108 are likewise patentable over the art of record. In addition, they include additional limitations that further distinguish over the art of record. For example, claims 93 recites a specific dosage amount of the claimed composition that is neither taught nor suggested in the applied art.

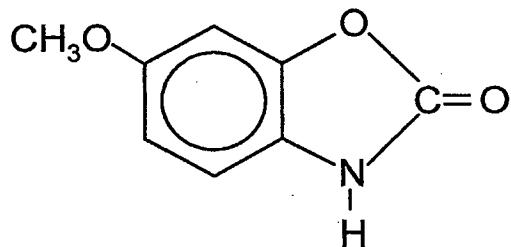
Claim 94 requires that the 6-MBOA be "obtained from a leafy and/or immature plant part of one or more monocotyledonous plants selected from the group consisting of corn, wheat, barley, rye, oats, rice, sorghum, millet, bamboo, Job's Tears, barley-like grasses, and wild grasses." The "meal" described in Chawan can be a processed corn product, such as taco shells and tortillas, neither of which are made from a leafy and/or immature plant part as required by claim 94. Claims 95-102 also specifically refer to plant parts, not foods made from processed seed grains such as those referred to in Chawan.

Claim 108 requires that "at least a portion of said 6-methoxy-2,3-benzoxazolinone is obtained by chemical synthesis". Chawan neither teaches nor suggests administering 6-BMOA

to a mammal to promote weight loss, let alone obtaining any portion of the 6-BMOA by chemical synthesis.

Claim 109 claims the composition in an isolated and/or extracted and/or purified form. Support for the composition being isolated and/or extracted and/or purified (e.g., concentrated) is found at page 8, lines 8, 11, 14 and 17, page 9, lines 2, 5, 8, 11 and 14, and page 14, lines 2-3. Chawan neither teaches nor suggests administering 6-BMOA to a mammal to promote weight loss, let alone obtaining any portion of the 6-BMOA in isolated and/or extracted and/or purified form.

New claim 110 alternatively claims a process for promoting weight loss and/or treating at least one of fibromyalgia, sleep disorder, mood disorder, hyperglycemia, arthritis, or substance addiction in a human by the administration of an amount of a composition comprising 6-methoxy-2,3-benzoxazolinone defined as:



or a pharmaceutically acceptable salt thereof sufficient to promote weight loss and/or treat at least one of fibromyalgia, sleep disorder, mood disorder, hyperglycemia, arthritis, or substance addiction in said human, wherein said administered composition comprises a daily dosage of between about 5 mcg and about 60 mg of said 6-methoxy-2,3-benzoxazolinone, wherein said composition is isolated and/or extracted and/or purified from at least one of (i) a leafy and/or immature plant part of one or more monocotyledonous plants or (ii) chemical synthesis.

Support for treating at least one of fibromyalgia, sleep disorder, mood disorder, hyperglycemia, arthritis, or substance addiction in a human is found in the Application at page 8, lines 13-18, page 9, lines 1-6, 10-15, page 10, line 23, page 11, lines 9-12, page 12, lines 18-21, and page 13, lines 23-25. New claims 111-113 are based on already existing claims.

Claims 110-113 are believed to be patentable for substantially the same reasons given above relative to claims 93-103 and 107-109. Chawan fails to teach or suggest providing the claimed composition in an *isolated* and/or *extracted* and/or *purified* form. There is no teaching

or suggestion in Chawan of isolating, extracting and/or purifying the claimed composition, particularly since Chawan does not even mention or suggest its existence in any of the disclosed food products. For this additional reason, Applicants submit that claims 93-103 and 107-109 are further patentable over the art of record.

Finally, Applicants are submitting newly discovered EP 0070016 A1 ("EP '016") in an Information Disclosure Statement. EP '016 discloses adding 6-MBOA to corn meal (*i.e.*, ground corn kernal), which, in turn, is blended with chicken feed to increase reproduction in chickens. The fact that 6-MBOA is added to corn meal blended with chicken feed to provide sufficient 6-MBOA to enhance chicken reproduction is further evidence that 6-MBOA is not found in significant quantities within corn kernal and food products made therefrom. Otherwise, EP '016 would simply teach adding a sufficient quantity of corn meal to the chicken feed to provide the desired quantity of 6-MBOA. Applicants also point out that chickens are not mammals or humans, and using 6-MBOA to promote reproduction in chickens does not provide any reasonable expectation of success in using this compound within the claimed range to promote weight loss in a mammal or human and/or to treat fibromyalgia, sleep disorder, mood disorder, hyperglycemia, arthritis, and/or substance addiction in a human.

In the event the Examiner finds any remaining impediment to a prompt allowance of this application that may be clarified through a telephone interview or which may be overcome by Examiner amendment, the Examiner is requested to contact the undersigned attorney.

Dated this 28<sup>th</sup> day of May 2008.

Respectfully submitted,



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